

Selections from the  
Medicis Aesthetics collection

Rx Only

**Dysport™**  
abobotulinumtoxinA  
300 Units for Injection

*Restylane®*

*Perlane®*

*Dysport, Restylane, and Perlane are not  
FDA-approved for combination use.*

Why wait? Talk to your doctor  
about *Dysport* today.

For more information visit [www.DysportUSA.com](http://www.DysportUSA.com)  
or call 866-222-1480.

Call your doctor for medical advice about side effects.  
You may report side effects to the FDA at 1-800-FDA-1088.

Please see Important Safety Information including  
Boxed Warning on pages 10–11 and Medication Guide  
on pages 14–17.

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All other trademarks are the property of their respective owners.



The  
Timing's  
Just  
Right!

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**Dysport™**  
abobotulinumtoxinA  
300 Units for Injection

*Dysport* is a prescription injection for temporary  
improvement in the look of moderate to severe frown  
lines between the eyebrows (glabellar lines) in adults  
less than 65 years of age

Please see Important Safety Information including Boxed Warning  
on pages 10–11 and Medication Guide on pages 14–17.

# The Timing's Just Right

Be true to the **you** you love

Prescription *Dysport*<sup>™</sup> is an injection used to temporarily improve the look of moderate to severe frown lines between the eyebrows in adults less than 65 years of age.

## The *Dysport* history

Though approved in the United States in April 2009, *Dysport* has a history of use in other countries since 1991. First approved outside the U.S. for aesthetic use in 2001, *Dysport* has steadily gained in popularity around the world. With its approval by the U.S. Food and Drug Administration, you, too, may join others worldwide who have been treated with *Dysport*.

## IMPORTANT SAFETY INFORMATION

**What is the most important information you should know about *Dysport*?**

**Spread of Toxin Effects:** In some cases, the effects of *Dysport* and all botulinum toxin products may affect areas of the body away from the injection site. These effects can cause symptoms of a serious condition called botulism. Symptoms of botulism can happen hours to weeks after injection and may include swallowing and breathing problems, loss of strength and muscle weakness all over the body, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, or loss of bladder control.

Swallowing and breathing problems can be life threatening and there have been reports of death.

The risk of symptoms is probably greatest in children and adults treated for muscle spasms, particularly in those patients who have underlying medical conditions that could make these symptoms more likely.

The toxic effects have been reported at doses similar to those used to treat muscle spasms in the neck. Lower doses, in both approved and unapproved uses, have also caused toxic effects. This includes treatment of children and adults for muscle spasms.

These effects could make it unsafe for you to drive a car, operate machinery, or do other dangerous activities.

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# Face Facts

## What causes frown lines?

Over time, repeated movement of the facial skin by the forehead muscles forms lines between the eyebrows.

## Not just age-related

Frown lines are "dynamic"—they happen because of the way a person's face moves. Because frown lines are created by facial movements, such as frowning or squinting, they may develop even in younger adults. *Dysport™* is used to treat moderate to severe frown lines in patients between the ages of 18 and 65.



The muscles in the treated area above and between the eyebrows contract and tighten, and can cause wrinkles. *Dysport* blocks the nerve signal that causes

these facial muscles to contract. This ultimately results in a localized reduction of muscle activity in the treated area and temporarily stops the tightening of these muscles.

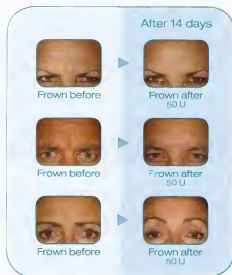
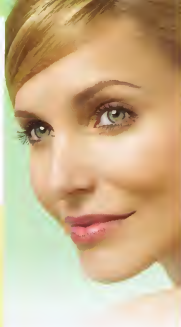
## IMPORTANT SAFETY INFORMATION

The dose of *Dysport* is not the same as or interchangeable with the dose of any other botulinum toxin product. The dose of *Dysport* cannot be compared to the dose of any other botulinum toxin product you may have used.

**Do not have *Dysport* treatment if you:** are allergic to *Dysport* or any of its ingredients (see the end of the Medication Guide for a list of ingredients), are allergic to cow's milk protein, had an allergic reaction to any other botulinum toxin product (such as Myobloc® or Botox®), or have a skin infection at the planned injection site.

**Please see Important Safety Information including Boxed Warning on pages 10–11 and Medication Guide on pages 14–17.**

These images are real, unaltered photographs of patients treated with *Dysport™* at maximum frown.



Individual results may vary.

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# Clinical Facts

Three double-blind, randomized, placebo-controlled, clinical studies evaluated the efficacy of *Dysport*™ for use in the temporary improvement of the appearance of moderate to severe glabellar lines. These 3 studies enrolled healthy adults (ages 19–75) with glabellar lines of at least moderate severity at maximum frown. Subjects were excluded if they had marked ptosis, deep dermal scarring, or a substantial inability to lessen glabellar lines, even by physically spreading them apart. The subjects in these studies received either *Dysport* or placebo. The total dose was delivered in equally divided aliquots to specified injection sites.

## What kind of improvement are you looking for?

**No downtime:** With *Dysport*, there is little to no downtime after injection.

**Visible results:** In clinical trials, the majority of patients (86% on average) had frown lines that improved from scores of “moderate” or “severe” to “none” or “mild,” respectively, as assessed at maximum frown by a physician at the 30-day evaluation, representing at least a 1-grade improvement on a 4-grade scale where 0 was none and 4 was severe. A 2+ grade improvement was considered a treatment success.

**Repeatable results:** In clinical trials, the efficacy of *Dysport* was demonstrated with up to 4 repeated treatments. Your results may vary. You should wait at least 90 days between treatments. The safety of *Dysport* has not been studied for more than 12 repeated treatments.

**Worldwide experience:** *Dysport* is used for aesthetic purposes in 34 countries. In U.S. clinical trials, *Dysport* safety was studied in more than 2400 aesthetic patients. A total of 376 patients were studied for efficacy of the product.

Please see Important Safety Information including Boxed Warning on pages 10–11 and Medication Guide on pages 14–17.

*Dysport*™—  
right on time!

## What about side effects?

The most common side effects are nose and throat irritation, headache, injection site skin reaction, upper respiratory tract infection, eyelid swelling, eyelid drooping, sinus inflammation, and nausea. In some cases, *Dysport* may cause serious side effects, such as swallowing or breathing problems, that may be life threatening. For more information on possible side effects of *Dysport*, please see the Important Safety Information including Boxed Warning on pages 10–11 and the Medication Guide on pages 14–17, or talk to your healthcare professional.

## IMPORTANT SAFETY INFORMATION

***Dysport* may not be right for you if:** you have surgical changes to your face, very weak muscles in the treatment area, your face looks very different from side to side, the injection site is inflamed, you have droopy eyelids or sagging eyelid folds, deep facial scars, thick oily skin, or if your wrinkles can't be smoothed by spreading them apart.

**Tell your doctor about all your medical conditions, including if you have:** a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS] or Lou Gehrig's disease), myasthenia gravis, or Lambert-Eaton syndrome), allergies to any botulinum toxin product, had any side effect from any botulinum toxin product in the past, a breathing problem (such as asthma or emphysema), swallowing problems, bleeding problems, diabetes, a slow heart beat or other problem with your heart rate or rhythm, plans to have surgery, had surgery on your face, weakness of your forehead muscles (such as trouble raising your eyebrows), drooping eyelids, or any other change in the way your face normally looks.

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# Visible Improvements

## Treatment with *Dysport*™

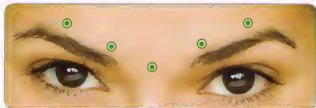
*Dysport* is a purified formulation that has been shown to deliver temporary improvements in moderate to severe frown lines, even with repeat treatments. So, the effect of repeat treatment with *Dysport* may be comparable to your first use!\*

With just 1 injection into each of 5 points between and over the eyebrows, *Dysport* stops the signal from the nerve to the muscles, ultimately resulting in a reduction of muscle activity and temporarily preventing contraction of the muscles that cause frown lines.

The untreated facial muscles still contract normally, allowing you to freely show facial expressions, such as laughing, in untreated areas.

You should not be treated with *Dysport* more frequently than every 90 days.

## Injection sites for *Dysport*

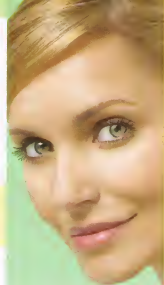


*Dysport* is given as 1 injection into each of 5 points between and over the eyebrows, ultimately resulting in a reduction of muscle activity and temporarily preventing contraction of the muscles that cause frown lines.

\*In clinical trials, the efficacy of *Dysport* was studied in a total of 376 patients and was demonstrated with up to 4 repeated treatments. The safety of *Dysport* has not been studied for more than 12 repeated treatments.

Please see Important Safety Information including Boxed Warning on pages 10–11 and Medication Guide on pages 14–17.

With *Dysport*™ the timing's just right!



## INDICATION

*Dysport* is a prescription injection for temporary improvement in the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults less than 65 years of age.

## IMPORTANT SAFETY INFORMATION

### Human Albumin

This product contains albumin taken from human plasma. Steps taken during donor screening and product manufacturing processes make the risk of spreading viral diseases extremely rare. In theory, there is also an extremely rare risk of contracting Creutzfeldt-Jakob disease (CJD). No cases of spread of viral diseases or CJD have ever been reported for albumin.

### Allergic Reaction to Injecting in the Skin

It is not known if an allergic reaction can be caused by injecting *Dysport* into the skin. The safety of treating excessive sweating with *Dysport* is not known.

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## IMPORTANT SAFETY INFORMATION

### What is the most important information you should know about *Dysport*™?

**Spread of Toxin Effects:** In some cases, the effects of *Dysport* and all botulinum toxin products may affect areas of the body away from the injection site. These effects can cause symptoms of a serious condition called botulism. Symptoms of botulism can happen hours to weeks after injection and may include swallowing and breathing problems, loss of strength and muscle weakness all over the body, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, or loss of bladder control.

Swallowing and breathing problems can be life threatening and there have been reports of death.

The risk of symptoms is probably greatest in children and adults treated for muscle spasms, particularly in those patients who have underlying medical conditions that could make these symptoms more likely.

The toxic effects have been reported at doses similar to those used to treat muscle spasms in the neck. Lower doses, in both approved and unapproved uses, have also caused toxic effects. This includes treatment of children and adults for muscle spasms.

These effects could make it unsafe for you to drive a car, operate machinery, or do other dangerous activities.

The dose of *Dysport* is not the same as or interchangeable with the dose of any other botulinum toxin product. The dose of *Dysport* cannot be compared to the dose of any other botulinum toxin product you may have used.

Do not have *Dysport* treatment if you: are allergic to *Dysport* or any of its ingredients (see the end of the Medication Guide for a list of ingredients), are allergic to cow's milk protein, had an allergic reaction to any other botulinum toxin product (such as Myobloc® or Botox®), or have a skin infection at the planned injection site.

***Dysport* may not be right for you if:** you have surgical changes to your face, very weak muscles in the treatment area, your face looks very different from side to side, the injection site is inflamed, you have droopy eyelids or sagging eyelid folds, deep facial scars, thick oily skin, or if your wrinkles can't be smoothed by spreading them apart.

**Tell your doctor about all your medical conditions, including if you have:** a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis, or Lambert-Eaton syndrome), allergies to any botulinum toxin product, had any side effect from any botulinum toxin product in the past, a breathing problem (such as asthma or emphysema), swallowing problems, bleeding problems, diabetes, a slow heart beat or other problem with your heart rate or rhythm, plans to have surgery, had surgery on your face, weakness of your forehead muscles (such as trouble raising your eyebrows), drooping eyelids, or any other change in the way your face normally looks.

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### Allergic Reaction to Injecting in the Skin

It is not known if an allergic reaction can be caused by injecting *Dysport*™ into the skin. The safety of treating excessive sweating with *Dysport* is not known.

### Common Side Effects

The most common side effects are nose and throat irritation, headache, injection site pain, injection site skin reaction, upper respiratory tract infection, eyelid swelling, eyelid drooping, sinus inflammation, and nausea.

**Tell your doctor about all the medicines you take,** including prescription and nonprescription medicines, vitamins and herbal and other natural products. Using *Dysport* with certain other medicines may cause serious side effects. **Do not start any new medicines while taking *Dysport* without talking to your doctor first.**

**Especially tell your doctor if you:** have received any other botulinum toxin product in the last four months, have received injections of botulinum toxin, such as Myobloc® (rimabotulinumtoxinB) or Botox® (onabotulinumtoxinA) in the past (be sure your doctor knows exactly which product you received), have recently received an antibiotic by injection, take muscle relaxants, take an allergy or cold medicine, or take a sleep medicine.

### Use In Specific Populations

*Dysport* should not be used in children or in women who are pregnant or breastfeeding.

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# A step-by-step guide to your *Dysport*<sup>™</sup> treatment

Here's what to expect<sup>\*</sup>:

## 1 The *Dysport* treatment consultation

Discuss your expectations with your doctor and whether you have any health conditions or allergies that could interfere with your treatment. See important safety information on the previous page. It's always a good idea to arrive early so you have plenty of time to fill out forms and ask staff any remaining questions you may have.

## IMPORTANT SAFETY INFORMATION

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal and other natural products. Using *Dysport* with certain other medicines may cause serious side effects. Do not start any new medicines while taking *Dysport* without talking to your doctor first.

**Especially tell your doctor if you:** have received any other botulinum toxin product in the last four months, have received injections of botulinum toxin, such as Myobloc<sup>®</sup> (rimabotulinumtoxinB) or Botox<sup>®</sup> (onabotulinumtoxinA) in the past (be sure your doctor knows exactly which product you received), have recently received an antibiotic by injection, take muscle relaxants, take an allergy or cold medicine, or take a sleep medicine.

### Use In Specific Populations

*Dysport* should not be used in children or in women who are pregnant or breastfeeding.

<sup>\*</sup> Though the experience described above is typical, the general routine at your doctor's office may differ, and individual results may vary.

Please see Important Safety Information including Boxed Warning on pages 10-11 and Medication Guide on pages 14-17.

## 2 The *Dysport*<sup>™</sup> treatment

Effective treatment requires 1 injection into each of 5 points between and over the eyebrows. Although office visit times may vary, the procedure generally takes about 10 to 20 minutes. Your healthcare professional will determine the exact placement of each injection to get results that are right for you.

## 3 After your *Dysport* treatment

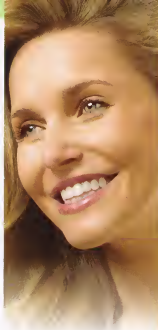
There is little to no downtime, and you can go about your day as usual! Ask your doctor about any precautions you should take after your treatment. Call your doctor or get medical help right away if you have any problems swallowing, speaking, or breathing. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

## 4 Follow-up

To maintain your improvements, you should discuss a treatment schedule with your doctor. As with any botulinum toxin product, you should wait at least 90 days between treatments. The efficacy of *Dysport* has not been established for more than 4 repeated treatments. The safety of *Dysport* has not been studied for more than 12 repeated treatments.

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abobotulinumtoxinA  
300 Units for Injection





**MEDICATION GUIDE**  
**DYSPORT™ (DIS-port)**  
**(abobotulinumtoxinA)**  
**Injection**

Read the Medication Guide that comes with DYSPORT™ before you start using it and each time DYSPORT™ is given to you. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. You should share this information with your family members and caregivers.

**What is the most important information I should know about DYSPORT™?**

**DYSPORT™ may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems after treatment with DYSPORT™:**

- **Problems swallowing, speaking, or breathing.** These problems can happen hours to weeks after an injection of DYSPORT™ usually because the muscles that you use to breathe and swallow can become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with DYSPORT™.
- People with certain breathing problems may need to use muscles in their neck to help them breathe. These patients may be at greater risk for serious breathing problems with DYSPORT™.
- Swallowing problems may last for several weeks. People who can not swallow well may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. People who already have swallowing or breathing problems before receiving DYSPORT™ have the highest risk of getting these problems.
- **Spread of toxin effects.** In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include:
  - loss of strength and muscle weakness all over the body
  - double vision
  - blurred vision and drooping eyelids
  - hoarseness or change or loss of voice (dysphonia)
  - trouble saying words clearly (dysarthria)
  - loss of bladder control
  - trouble breathing
  - trouble swallowing

These symptoms can happen hours to weeks after you receive an injection of DYSPORT™.

These problems could make it unsafe for you to drive a car or do other dangerous activities. See "What should I avoid while receiving DYSPORT™?"

**What is DYSPORT™?**

DYSPORT™ is a prescription medicine that is injected into muscles and used:

- to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults
- to improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults younger than 65 years of age for a short period of time (temporary)

CD is caused by muscle spasms in the neck. These spasms cause abnormal position of the head and often neck pain. After DYSPORT™ is injected into muscles, those muscles are weakened for up to 12 to 16 weeks or longer. This may help lessen your symptoms.

Frown lines (wrinkles) happen because the muscles that control facial expression are used often (muscle tightening over and over). After DYSPORT™ is injected into the muscles that control facial expression, the medicine stops the tightening of these muscles for up to 4 months.

It is not known whether DYSPORT™ is safe or effective in children under 18 years of age.

It is not known whether DYSPORT™ is safe or effective for the treatment of other types of muscle spasms. It is not known whether DYSPORT™ is safe or effective for the treatment of other wrinkles.

**Who should not take DYSPORT™?**

**Do not take DYSPORT™ if you:**

- are allergic to DYSPORT™ or any of the ingredients in DYSPORT™. See the end of this Medication Guide for a list of ingredients in DYSPORT™
- are allergic to cow's milk protein
- had an allergic reaction to any other botulinum toxin product such as Myobloc® or Botox®
- have a skin infection at the planned injection site

**What should I tell my doctor before taking DYSPORT™?**

**Tell your doctor about all your medical conditions, including if you have:**

- a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome). See "What is the most important information I should know about DYSPORT™?"
- allergies to any botulinum toxin product
- had any side effect from any botulinum toxin product in the past
- a breathing problem, such as asthma or emphysema
- swallowing problems
- bleeding problems
- diabetes
- a slow heart beat or other problem with your heart rate or rhythm
- plans to have surgery
- had surgery on your face



- weakness of your forehead muscle (such as trouble raising your eyebrows)
- drooping eyelids
- any other change in the way your face normally looks

#### **Tell your doctor if you:**

- are pregnant or plan to become pregnant. It is not known if DYSPORT™ can harm your unborn baby
- are breast-feeding or planning to breast-feed. It is not known if DYSPORT™ passes into breast milk

**Tell your doctor about all the medicines you take**, including prescription and nonprescription medicines, vitamins and herbal and other natural products. Using DYSPORT™ with certain other medicines may cause serious side effects. **Do not start any new medicines while taking DYSPORT™ without talking to your doctor first.**

#### **Especially tell your doctor if you:**

- have received any other botulinum toxin product in the last four months
- have received injections of botulinum toxin, such as Myobloc® (Botulinum Toxin Type B)\* or Botox® (Botulinum Toxin Type A)\* in the past; be sure your doctor knows exactly which product you received
- have recently received an antibiotic by injection
- take muscle relaxants
- take an allergy or cold medicine
- take a sleep medicine

#### **Ask your doctor if you are not sure if your medicine is one that is listed above.**

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

#### **How should I take DYSPORT™?**

- DYSPORT™ is an injection that your doctor will give you
- DYSPORT™ is injected into the affected muscles
- Your doctor may give you another dose of DYSPORT™ after 12 weeks or longer, if it is needed
- If you are being treated for CD, your doctor may change your dose of DYSPORT™, until you and your doctor find the best dose for you
- The dose of DYSPORT™ is not the same as the dose of any other botulinum toxin product

#### **What should I avoid while taking DYSPORT™?**

DYSPORT™ may cause loss of strength or general muscle weakness, blurred vision, or drooping eyelids within hours to weeks of taking DYSPORT™. **If this happens, do not drive a car, operate machinery, or do other dangerous activities. See "What is the most important information I should know about DYSPORT™?"**

#### **What are the possible side effects of DYSPORT™?**

**DYSPORT™ can cause serious side effects. See "What is the most important information I should know about DYSPORT™?"**

#### **Other side effects of DYSPORT™ include:**

- dry mouth
- injection site discomfort or pain
- tiredness
- headache
- neck pain
- muscle pain
- eye problems: double vision, blurred vision, decreased eyesight, problems with focusing the eyes (accommodation), drooping eyelids, swelling of the eyelids
- allergic reactions: Symptoms of an allergic reaction to DYSPORT™ may include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you get wheezing or asthma symptoms, or if you get dizzy or faint

**Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of DYSPORT™. For more information, ask your doctor or pharmacist.**

**Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

#### **General information about DYSPORT™:**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about DYSPORT™. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about DYSPORT™ that is written for healthcare professionals. For more information about DYSPORT™ call 877-397-7671 or go to [www.dysport.com](http://www.dysport.com) or [www.DysportUSA.com](http://www.DysportUSA.com).

#### **What are the ingredients in DYSPORT™?**

Active ingredient: (botulinum toxin Type A)  
Inactive ingredients: human albumin, and lactose. DYSPORT™ may contain cow's milk protein.

Issued May 2009

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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# Notes

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